UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,895	08/06/2003	Philippe Despres	241161US0DIV	7352

22850 7590 11/29/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,895	DESPRES ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-7,10-14,17-23 and 25-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *3-7,10-14,17-23 and 25-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed August 6, 2003 is acknowledged and entered. Claims 3-7, 10-14, 17-23 and 25-65 are pending and subject to the following restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3-7, drawn to a polynucleotide encoding SEQ ID NO: 1, classified in class 536, subclass 23.72.

II. Claims 10-14, drawn to a polynucleotide encoding SEQ ID NO: 2, classified in class 536, subclass 23.72.

III. Claims 17-23, drawn to a polynucleotide encoding SEQ ID NO: 1 and 2, classified in class 536, subclass 23.72.

IV. Claims 29-33, drawn to a method of inducing apoptosis with the polypeptide SEQ ID NO: 1 linked to the polypeptide SEQ ID NO: 2, classified in class 435, subclass 5.

V. Claims 34-41, drawn to a method of screening for peptides capable of inducing apoptosis utilizing a peptide linked to SEQ ID NO: 2, classified in class 435, subclass 5.

VI. Claims 42, 43 and 50, drawn to the polypeptide SEQ ID NO: 3, classified in class 530, subclass 300.

VII. Claims 44-49, drawn to a polynucleotide encoding SEQ ID NO: 3, classified in class 536, subclass 23.72.

VIII. Claims 51-54, drawn to a method of inducing apoptosis with the polypeptide SEQ ID NO: 3, classified in class 435, subclass 5.

IX. Claims 55-59, drawn to a method of screening for peptides capable of inducing apoptosis utilizing SEQ ID NO: 3, classified in class 435, subclass 5.

X. Claim 60, drawn to a monoclonal antibody that binds DEN-1 M protein, classified in class 424, subclass 130.1.

XI. Claim 61, drawn to a monoclonal antibody that binds DEN-2 M protein, classified in class 424, subclass 130.1.

XII. Claim 62, drawn to a plasmid deposited at the CNCM under the accession number I-2684, classified in class 435, subclass 320.1.

XIII. Claim 63, drawn to a plasmid deposited at the CNCM under the accession number I-2686, classified in class 435, subclass 320.1.

XIV. Claim 64, drawn to a plasmid deposited at the CNCM under the accession number I-2685, classified in class 435, subclass 320.1.

XV. Claim 65, drawn to a plasmid deposited at the CNCM under the accession number I-2475, classified in class 435, subclass 320.1.

3. The inventions are distinct, each from the other because of the following reasons:

a) Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not rely

solely on the patentability of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not rely solely on the patentability of the subcombination as claimed because SEQ ID NO: 2 can be combined with any peptide to result in the claimed combination (see claims 34-41). The subcombination has separate utility. The polynucleotide encoding SEQ ID NO: 2 is useful in a method with a sequence other than SEQ ID NO: 1. Further, SEQ ID NO: 1 and 2 can be used separately as antigenic markers.

b) Inventions (I-II) and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, SEQ ID NO: 1 can be used in a materially different process of using, such as in an immunoassay to detect antibodies. SEQ ID NO: 2 can be used in a materially different process of using, such as in an immunoassay to detect antibodies.

c) Inventions I and (V-XV) are distinct inventions. SEQ ID NO: 1 is not SEQ ID NO: 3, the polypeptide or the polynucleotide encoding it. The sequences have different encoded amino acids in different orders. SEQ ID NO: 1 is not required to practice the methods of Inventions VIII and IX. SEQ ID NO: 1 is not bound by the antibodies of Inventions X and XI. SEQ ID NO: 1 is not present in the plasmids of Inventions XII-XV.

d) Inventions II and V are related as product and process of use. In this case, the polynucleotide encoding SEQ ID NO: 2 can be used in a materially different process of using, such as in an immunoassay to detect antibodies.

e) Inventions II and (VI-XV) are distinct inventions. SEQ ID NO: 2 is not the same as SEQ ID NO: 3, the polypeptide or the polynucleotide encoding it. The sequences have different encoded amino acids in different orders. SEQ ID NO: 2 is not required to practice the methods of Inventions VIII and IX. SEQ ID NO: 2 is not bound by the antibodies of Inventions X and XI. SEQ ID NO: 2 is not present in the plasmids of Inventions XII-XV.

f) Inventions III and (IV-V) are related as product and process of use. In this case, the polynucleotide encoding SEQ ID NO: 1 and 2 can be used in a materially different process of using, such as in an immunoassay to detect antibodies.

g) Inventions III and (VI-XV) are distinct inventions. SEQ ID NO: 1 and 2 are not the same as SEQ ID NO: 3, the polypeptide or the polynucleotide encoding it. The sequences have different encoded amino acids in different orders. SEQ ID NO: 1 and 2 are not required to practice the methods of Inventions VIII and IX. SEQ ID NO: 1 and 2 are not bound by the antibodies of Inventions X and XI. SEQ ID NO: 1 and 2 are not present in the plasmids of Inventions XII-XV.

h) Inventions IV and V are distinct methods. The method of Invention IV is drawn to inducing apoptosis by administering the polypeptides SEQ ID NO: 1 and 2. The method of Invention V is drawn to screening peptides capable of inducing apoptosis, wherein the peptides are linked to SEQ ID NO: 2. These methods do not share method steps or reagents beyond SEQ ID NO: 2. A search for Invention IV is not expected to reveal literature related to methods of screening peptides for apoptotic activity.

i) Inventions (IV and V) and (VI-XV) are distinct inventions. The method of inducing apoptosis with SEQ ID NO: 1 and 2 is not required or related to SEQ ID NO: 3, the polypeptide

or the polynucleotide encoding it. The method of screening for peptides with SEQ ID NO: 2 is not required or related to SEQ ID NO: 3, the polypeptide or the polynucleotide encoding it. The methods of inducing apoptosis with SEQ ID NO: 3 are not required to practice the methods of Inventions IV or V. Inventions IV and V do not require the monoclonal antibodies or vectors of Inventions X-XV.

j) Inventions VI and VII are patentably distinct products. The polypeptide of Group VI and polynucleotide of Group VII are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. Searching the inventions of Groups VI and VII together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups VI and VII have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive.

k) Inventions VI and (VIII-IX) are related as product and process of use. In the instant case, the polypeptide SEQ ID NO: 3 can be used in a materially different process of using, such as in an immunoassay to detect antibodies.

l) Inventions VII and (VIII-IX) are distinct inventions. The polynucleotide of Invention VII is not required to practice the methods of VIII and IX, which require the encoded polypeptide.

m) Inventions (VI, VII, X-XV) are all distinct from each other. The polypeptides, polynucleotides, vectors and antibodies are all distinct products. The products are not disclosed as capable of use together. They have different structures and different functions. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. Antibodies are complex structures comprising 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope.

n) Inventions (X-XV) and (VIII-IX) are distinct inventions. The methods of inducing apoptosis and screening for peptides do not require the antibodies and vectors of Inventions X-XV.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature/sequence search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper. A search for any more than one group would be a serious search burden. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in

compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
November 28, 2005